**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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|---|---|
| McNeil-PPC, Inc. and McNeil Consumer Healthcare,<br><br>Plaintiffs,<br><br>v.<br><br>GlaxoSmithKline Consumer Healthcare LP,<br><br>Defendant. | Civil Action No. 15 CV 01866 (LTS) |

**DEFENDANT'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

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## INTRODUCTION

Plaintiffs McNeil-PPC, Inc. and McNeil Consumer Healthcare (collectively, "McNeil") rushed to court hoping to derail the launch of Flonase Allergy Relief, a new over-the-counter ("OTC") allergy medication by Defendant GlaxoSmithKline Consumer Healthcare, L.P. ("GSK"), contending that the following two claims in GSK's advertisements are literally false:

- "Flonase® Outperforms The #1 Allergy Pill"; and
- Flonase controls "6 key inflammatory substances that cause our symptoms," while "the leading allergy pill" controls only one.

McNeil argues that both claims are literally false or false by necessary implication because Zyrtec must be considered the "#1" and "leading" single-ingredient allergy pill based on its sales figures.[1] McNeil further asserts that GSK's advertisements are literally false or false by necessary implication because (1) no studies support a claim that Flonase outperforms Zyrtec; and (2) Zyrtec, as the (supposedly) leading allergy pill, does not control fewer *symptoms* than Flonase. McNeil presented only the declarations of two McNeil employees to support its bold allegations, and asked the Court to issue the injunction without allowing any discovery. *See* Hr'g Tr. at 6:17-7:6, Mar. 13, 2015.

McNeil's evidence falls woefully short of the standard for granting a preliminary injunction and, indeed, is demonstrably false. First, McNeil cannot prove the requisite threshold issue: that GSK's advertisements necessarily and unambiguously will be interpreted by consumers to refer to Zyrtec rather than Claritin. A claim based on a "literal falsity argument ***fails*** if the statement or image" at issue "can reasonably be understood as conveying different messages." *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007)

[1] Although McNeil's motion references its Benadryl product, too, McNeil asserted at the March 13, 2015, hearing that its claim was based on its contention that Zyrtec was the leading allergy pill. Hr'g Tr. 3:20-21.

(emphasis added) (quoting *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 274 (4th Cir. 2002)). Although McNeil contends that GSK's advertising must refer to McNeil's Zyrtec product because Zyrtec outsells its single-ingredient competitors, in fact, sales data from both Information Resources, Inc. ("IRI") and Nielsen show that *Claritin* is the leading seller.

Leaving aside for the moment whether the dollar value of a product's sales is the unambiguously appropriate measure of what constitutes the "#1" or "leading" product, Zyrtec is simply not the sales leader. McNeil's sales figures, which allegedly show Zyrtec as the leader in both dollar value and unit sales, appear to be based on data from Nielsen that McNeil knows includes neither key Claritin products nor sales data from an important segment of retailers: convenience stores. When those figures are included, Zyrtec's sales lag behind those of Claritin:

| | **Claritin (YE 12/28/14)** | **Zyrtec (YE 12/28/14)** | **Claritin (52 Wks ending 03/08/15)** | **Zyrtec (52 Wks ending 03/08/15)** |
|---|---|---|---|---|
| **IRI data, $ value** | [redacted] | [redacted] | [redacted] | [redacted] |
| **IRI data, units** | [redacted] | [redacted] | [redacted] | [redacted] |
| | | | | |
| **Nielsen + IRI Convenience Store, $ value** | [redacted] | [redacted] | [redacted] | [redacted] |
| **Nielsen + IRI Convenience Store, units** | [redacted] | [redacted] | [redacted] | [redacted] |

McNeil well knows the truth about the relative sales of Claritin and Zyrtec. In public statements, as recently as last month, McNeil itself has admitted that Claritin, not Zyrtec, is the "category leader." Decl. of Amardeep Kahlon ("Kahlon") ¶ 19. In February, McNeil's marketing director and corporate representative, Colleen Sellers, publicly admitted that ***Claritin*** is the "category leader," with Zyrtec's market share lagging behind that of Claritin. *Id.* ¶ 21.

And, in its submission for a marketing award in 2014, McNeil admitted that "Claritin has more users than any other brand" and that "[a]nalysis of IRI purchase panel data revealed a large group…who were regularly treating with Claritin." *Id.* ¶ 22. These damning admissions fly in the face of Ms. Seller's sworn statements to the Court and the unsubstantiated sales figures that McNeil submits in support of its motion. Additionally, consumer research supports that Claritin is ahead of Zyrtec based on non-financial metrics, such as brand awareness and loyalty, further undermining McNeil's claim that Zyrtec unambiguously is "#1." *Id.* ¶ 15.

McNeil cannot prove literal falsity for other reasons as well. In order to persuade the Court that the merits of this case are simple enough to assess on a preliminary injunction motion, McNeil represented that "there is no testing that demonstrates superiority for Flonase over…Zyrtec…." Compl. ¶ 4. In fact, Flonase outperformed Zyrtec in alleviating allergy nasal symptoms in two well-designed and peer-reviewed studies. Declaration of Vidhu Dev ("Dev") ¶¶ 14-18. McNeil's claimed ignorance of these studies is surprising because GSK specifically alerted McNeil to at least one in pre-litigation correspondence. *Id.* ¶ 16. In contrast to these studies, to support its allegation that Flonase does *not* outperform Zyrtec, McNeil relies solely on a single study of *limited duration* that—despite the more limited time period—actually showed that Flonase had a greater effect than Zyrtec on total nasal symptom relief. Although the difference was insignificant over the study's short duration, it was trending towards statistical significance.

Similarly, McNeil cannot show that GSK's commercial falsely states that Flonase treats six *symptoms*, whereas the leading allergy pill only controls one. In fact, a plain reading of GSK's advertisement shows that it truthfully tells consumers how Flonase (an intranasal corticosteroid) works compared to single-ingredient antihistamines, such as Claritin (and Zyrtec).

Antihistamines such as Claritin (and Zyrtec) block only the inflammatory substance histamine, while Flonase blocks six key inflammatory substances: histamine, cytokine, prostaglandin, tryptase, chemokines, and leukotriene. Because McNeil cannot dispute that the words of the Flonase ads refer literally only to six "inflammatory substances," McNeil stretches to rely on the doctrine of "false by necessary implication." GSK's ads, however, specifically illustrate the six "inflammatory substances" that Flonase controls and make no reference, written or visual, to any symptoms. In this context, GSK's statements are simply not an "*unambiguous* message" that must be read as McNeil contends. *See Time Warner*, 497 F.3d at 158 (emphasis original).

Finally, McNeil cannot meet the high standard for a preliminary injunction because the balance of hardships tips decidedly in favor of GSK. Whereas McNeil relies merely on a presumption of harm and conclusory allegations, GSK will suffer truly irreparable and specific harm from an improvidently granted injunction. The beginning of a product launch is absolutely crucial to its success. GSK already has spen [redacted] advertising Flonase. A preliminary injunction would require GSK to change the [redacted] of in-store displays, television commercials, radio commercials, print advertisements and Internet advertisements that contain the claims at issue. In particular, GSK would have to hire individuals to remove [redacted] of in-store displays at [redacted] of stores, which would be a massive undertaking. A preliminary injunction in this case would be particularly devastating as GSK largely will miss the primary allergy season, and part of the limited period of time it has on the OTC market before generic versions become available. Moreover, Flonase's reputation will be tainted in the minds of consumers and retailers. Dev ¶ 7; Kahlon ¶¶ 44-45.

In short, McNeil does not come close to making the "clear showing" that it is entitled to the "extraordinary and drastic" equitable remedy it seeks. *Silberstein v. Aetna*, No. 13 CIV.

8759, 2014 WL 1388790, at *2 (S.D.N.Y. Apr. 9, 2014).

## FACTUAL BACKGROUND

GSK is one of the world's leading pharmaceutical and healthcare companies, which is committed to providing products that make consumers' lives better. This case is about different types of OTC allergy medications and the recent OTC launch of GSK's product Flonase.

### I. CLARITIN AND THE HISTORY OF OTC ALLERGY MEDICATIONS

There are different types of allergy medications that are available OTC to help consumers relieve allergy symptoms. Dev ¶¶ 5-6. Products like Claritin, Zyrtec, and Allegra are antihistamines that typically are taken in a pill form. *Id.* ¶ 5. Another type of allergy medication that is available OTC is intranasal corticosteroids like Nasacort and Flonase, which are taken in the form of a nasal spray. *Id.* ¶ 6. As discussed below, intranasal corticosteroids have a different mechanism of action as compared to their antihistamine pill competitors. *Id.*

Claritin was introduced in 2002 as the first non-drowsy antihistamine to become available without a prescription. Kahlon ¶ 11. As the first product in the non-drowsy antihistamine OTC category, Claritin enjoyed a major advantage and spent substantial sums on advertising and marketing the efficacy and non-drowsy nature of its formula. *Id.* As a result, Claritin quickly became a well-recognized and popular brand, which it continues to be today. *Id.* For the past more than 12 years, Claritin has widely and prominently advertised itself, including through national television and radio commercials, Internet and print advertisements, and in-store displays. *Id.* ¶ 12. In addition, Claritin has run significant public relations campaigns, which have generated further awareness of Claritin among consumers. *Id.*

No doubt inspired by Claritin's success, other challengers to Claritin have entered the market with different antihistamine pills of their own. *Id.* ¶ 13. For example, Zyrtec hit the market in 2008, followed by Allegra in 2011, and both Mucinex Allergy and QlearQuil Allergy

last year. *Id.* Despite aggressive marketing campaigns by these new entrants, Claritin has remained the leader across multiple metrics. *Id.* ¶ 14. As discussed in the Declaration of Prof. Ran Kivetz, Claritin is the #1 single-ingredient allergy pill according to data provided by third-party sources Nielsen and IRI, and is ahead of Zyrtec in terms of both dollar sales and unit sales. Decl. of Prof. Ran Kivetz ("Kivetz") ¶¶ 17-18.

In addition, Claritin remains ahead of Zyrtec in non-financial metrics, such as brand awareness and brand loyalty. Kahlon ¶ 15. For instance, the 2014 U.S. Study of Allergies, a third-party survey designed to monitor allergy sufferers' treatment choices, made the following findings with respect to Claritin and Zyrtec in 2014: [redacted] *Id.* Further, according to the Brand Keys Customer Loyalty Engagement Index ("CLEI") for both years 2014 and 2015, Claritin had the highest level of consumer engagement *vis-à-vis* expectations (which has been recognized as "defin[ing] how successful brands will be") in the category of OTC allergy medications. *Id.* ¶ 16.

**A. McNeil Has *Admitted* That Claritin Is The "Category Leader"**

McNeil well knows that its Zyrtec product still lags behind Claritin. Just last month, on February 6, 2015, weeks after Flonase began using the "#1" and "leading allergy pill" claims, McNeil's Group Brand Director, Allergy and Eyecare, Colleen Sellers, ***who signed a declaration in this case under penalty of perjury stating that Zyrtec is the #1 single-ingredient OTC allergy***

***pill***, Decl. of Colleen Sellers ("Sellers") ¶ 7, repeatedly referred to Claritin as the "category leader" during a presentation she gave at the Association of National Advertisers' (ANA) 2015 brand Masters Conference, according to an article summarizing that presentation. Kahlon ¶ 20. At the conference, Ms. Sellers talked in detail about Zyrtec's strategy of targeting the "category leader," Claritin. *Id.* ¶ 21. Ms. Sellers was reported as saying that by November 2014, Claritin had 0.8% more market share than Zyrtec, and that "on the eve of the ANA conference, the difference was down to half a point," thus acknowledging that Claritin was still ahead. *Id.*

In fact, McNeil's entire marketing strategy for Zyrtec apparently has been to target Claritin as the leading allergy pill. For example, in a recent submission for a 2014 North American Effie Award (an award given by Effie Worldwide for effective marketing), McNeil describes its marketing campaign, "Muddle No More," as a direct attack on the stronghold that McNeil perceived Claritin to have on what they described as "Claritin Complacents." *Id.* ¶ 22. McNeil stated:

> In order to grow ZYRTEC®'s business, we needed to get users of other brands to try it. ***Claritin has more users than any other brand***, and a lot of them have pretty severe allergies. ***Analysis of IRI purchase panel data*** revealed a large group of heavy allergy sufferers who were ***regularly treating with Claritin***. This group represented a significant potential source for new ZYRTEC® users

*Id.*

**B. Introduction of OTC Nasal Sprays**

In 2014, Nasacort entered the market as the first intranasal corticosteroid (the same type of product as Flonase) to be available OTC. *Id.* ¶ 33. The mechanism of action of intranasal corticosteroids like Nasacort and Flonase differs from antihistamine products that are delivered via a pill like Claritin, Zyrtec and Allegra. Dev ¶¶ 5-6. When the immune system recognizes the presence of allergens such as pollen or ragweed, it responds by producing antibodies, which in

turn bind to receptors on immune cells, triggering the release of allergic substances such as histamines, cytokines, prostaglandins, tryptases, chemokines and leukotrienes. *Id.* ¶ 4. It is those allergic substances that lead to symptoms such as nasal congestion. *Id.*

Antihistamines like Claritin, Zyrtec and Allegra block histamine receptors, thereby preventing the histamines from escalating the immune response that results in allergic symptoms. *Id.* ¶ 5. Intranasal corticosteroids like Flonase and Nasacort work differently by targeting not only histamines, but also other allergic substances such as cytokines, prostaglandins, tryptases, chemokines and leukotrienes. *Id.* ¶ 6. Intranasal corticosteroids, therefore, affect the allergic response more broadly, hindering numerous immune pathways that cause allergy symptoms. *Id.* In addition, as intranasal sprays (as opposed to pills), these medications are delivered directly to the nasal passage to prevent and relieve nasal symptoms. *Id.*

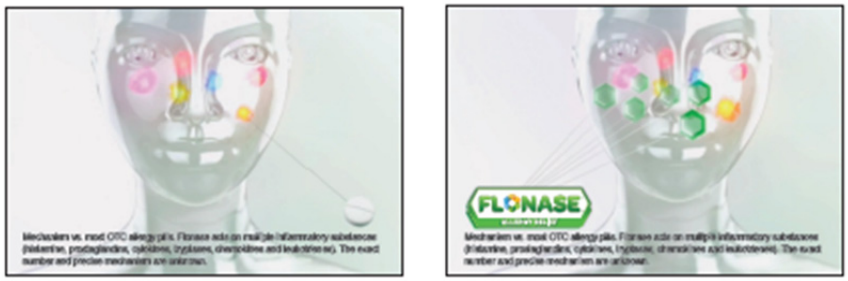
## II. THE INTRODUCTION OF FLONASE OTC

GSK received approval from the Food and Drug Administration on July 23, 2014. Kahlon ¶ 38. The next day, GSK began pre-marketing efforts for Flonase through the launch of a "coming soon" website, paid social media, and the launch of a relationship marketing program. *Id.* GSK began advertising Flonase in early January 2015 to raise consumer interest before the product became available in stores on February 4, 2015. *Id.* ¶ 39. Among the statements that GSK has made in advertising Flonase is that Flonase "Outperforms the #1 Allergy Pill." *Id.* As McNeil admits, there are studies showing that "Flonase [is] more effective in treating nasal allergy symptoms than Claritin." Dev ¶ 12.[2]

Another claim that GSK makes in its advertisements is to describe Flonase's mechanism

[2] And as discussed below, contrary to McNeil's assertion in this litigation that "there is no testing that demonstrates superiority for Flonase over . . . Zyrtec," there are, in fact, studies that support that Flonase statistically significantly improved nasal symptoms compared to Zyrtec. *Id.* ¶¶ 14-18.

of action because intranasal corticosteroids are still a relatively new concept for consumers compared to antihistamine products such as Claritin and its followers. Kahlon ¶ 30. In television commercials for Flonase, GSK explains: "[w]hen we breathe in allergens, our bodies react by over-producing ***six key inflammatory substances*** that cause our symptoms," and that "[t]he leading allergy pill only controls one. Flonase controls six. And 6 > 1." *Id.* ¶ 31. Along with this voiceover, the commercial shows a dramatization of how the different substances are produced by the body and targeted by Flonase, as seen in the below screenshots:




*Id.*

When Nasacort was launched in 2014, it also distributed advertisements describing how it works as an intranasal corticosteroid. For example, in a television commercial, Nasacort explained: "Your symptoms aren't caused by allergens, they're caused by your body's chemical responses to them. ***Antihistamines target only one of these responses.*** For some that's not good enough. Introducing Nasacort Allergy 24 Hour. Its powerful anti-inflammatory ***stops more***—relieving your worst nasal allergy symptoms…." *Id.* ¶ 34. And, like the Flonase commercial, Nasacort's commercial showed a dramatization of the allergic substances it targets:


*Id.* McNeil never sued Nasacort regarding these claims. *Id.* ¶ 35.

GSK has invested heavily in the launch of Flonase. *Id.* By the end of March, it will have spent [redacted] on advertising and marketing Flonase. *Id.* ¶ 42. GSK also will have distributed [redacted] in-store displays (the majority of which contain the claims "Helps Block 6 Allergic Substances, Not Just One," and/or "Outperforms the #1 Allergy Pill") across [redacted] retail locations. *Id.* Similarly, GSK has placed in stores [redacted] education boxes and [redacted] acrylic header cards, which also feature the claims at issue in this case. *Id.*

As discussed in detail in the Declaration of Amardeep Kahlon, the removal, reproduction, and replacement of the Flonase advertisements would be devastating to the Flonase brand and would cripple its launch. *Id.* ¶ 43-45. Not only would such an undertaking be extremely burdensome and disruptive, but it also would harm Flonase's reputation with consumers and retailers. *Id.* ¶ 43. Retailers would be angered if an injunction required GSK to remove [redacted] of in-store displays and [redacted] education boxes from retail locations across the country. *Id.* Moreover, by the time that GSK creates, produces and sets up new advertisements in stores across the country, GSK would have missed the primary allergy season. *Id.* ¶ 45. The issuance of a preliminary injunction at this point would be particularly

harmful because Flonase has only a limited period of time before generic versions of Flonase likely will be on the market, and thus compete with Flonase. Dev ¶ 7. Thus, a preliminary injunction effectively would ruin Flonase's launch in ways that GSK simply cannot regain. Kahlon ¶ 45.

## ARGUMENT

A preliminary injunction "is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (citations omitted); *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 22 (2008). A moving party must show more than a mere "possibility" of irreparable harm. *Winter*, 555 U.S. at 22. Instead, a "plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Id.* at 20; *see Salinger v. Colting*, 607 F.3d 68, 80 (2d Cir. 2010) (*citing eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006)). McNeil has not met its burden.

### I. MCNEIL IS NOT LIKELY TO SUCCEED ON THE MERITS

To establish a false advertising claim under 15 U.S.C. § 1125(a)(1), "a plaintiff must prove the following elements: (1) the defendant has made a false or misleading statement; (2) the false or misleading statement has actually deceived or has the capacity to deceive a substantial portion of the intended audience; (3) the deception is material in that it is likely to influence purchasing decisions; [and] (4) there is a likelihood of injury to plaintiff, such as declining sales or loss of goodwill. . . ." *Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp.*, 348 F. Supp. 2d 165, 178 (S.D.N.Y. 2004) (Swain, J.). McNeil's evidence falls far short on each element.

### A. Plaintiffs Are Limited to Theories of "Literal Falsity" on this Motion

To avoid subjecting itself and its scant evidence to discovery by GSK, McNeil agreed to base its motion only on the argument that GSK's claims are "literally false" or "literally false by necessary implication." Hr'g Tr. at 27:13-28:18. Therefore, McNeil must make a clear showing that it will prove the following at trial:

**Claim 1: "Outperforms the #1 Allergy Pill"**:

- that references to the "#1 Allergy Pill" will literally, necessarily, and unambiguously be interpreted by consumers as a reference to Zyrtec, and that
- even if so, it is actually false to say that Flonase outperforms Zyrtec; and

**Claim 2: Flonase controls "Six Inflammatory Substances" while the "leading allergy pill" controls only one**:

- that references to the "leading allergy pill" will literally, necessarily, and unambiguously be interpreted by consumers as a reference to Zyrtec ;
- that "six inflammatory ***substances***" will literally, necessarily, and unambiguously imply control of six allergy ***symptoms***; and
- that it is false to say that Flonase provides more symptom relief than Zyrtec.

To succeed, McNeil cannot merely show that its own interpretation is plausible, but must prove that the challenged statements are literally and ***unambiguously*** false. *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d at 158. If there is a reasonable alternative interpretation of the claim that is true, the statement is not literally false. *Id.*; *see also Coors Brewing Co. v. Anheuser-Busch Companies, Inc.*, 802 F. Supp. 965, 969 (S.D.N.Y. 1992); *Buetow v. A.L.S. Enters. Inc.*, 650 F.3d 1178, 1185 (8th Cir. 2011) ("When an ad 'can reasonably be understood as conveying different messages, [a] literal falsity argument must fail.'") (citation omitted).

### B. "Outperforms The #1 Allergy Pill" Is Not A Literal And Unambiguous Reference To Zyrtec

The first claim that McNeil seeks to enjoin is that Flonase "OUTPERFORMS THE #1 ALLERGY PILL* Total nasal symptoms vs. leading allergy pill." Pls.' Mem. at 5-6; Hr'g Tr. at

3:15-21. McNeil stipulated to the Court, for the purposes of this motion, that if this comparison to "The #1 Allergy Pill" is found to be a reference to Claritin, GSK has valid and truthful scientific support for this claim. Hr'g Tr. at 24:3-13. Therefore, if McNeil cannot establish that GSK's references to "the #1 allergy pill" and "leading allergy pill" are literally, necessarily, and unambiguously a comparison to McNeil's single-ingredient Zyrtec pills, McNeil loses.

**1. GSK's Advertisements Do Not Unambiguously Refer To Zyrtec**

McNeil cannot make this showing. First, GSK's advertisements do not expressly refer to "Zyrtec" by name. It is therefore entirely likely that someone could interpret the GSK's reference to the #1 allergy pill to be a reference to Claritin, the trailblazer in the category and the well-recognized leader that has been on the market and supported by extensive advertising for over 12 years. *See* Kahlon ¶¶ 11-12; Kivetz ¶¶ 31-33. Indeed, "number one" claims are consistently recognized by courts as being capable of being "reasonably interpreted in different ways by different consumers." *Rexall Sundown, Inc. v. Perrigo Co.*, 651 F. Supp. 2d 9, 34 (E.D.N.Y. 2009) ("No. 1 Dr. Recommended Joint Care Brand" in context was not literally false, and at worst ambiguous).[3]

GSK's advertisements also do not purport to be based on "dollar" or "unit" sales and therefore their accuracy cannot be judged solely by those metrics. In fact, while McNeil may contend that such metrics are the only appropriate ones, it presents no evidence to support that contention. Consumers, who are generally not privy to a manufacturer's sales figures, may interpret "the #1 allergy pill" and the "leading allergy pill" in the context of the Flonase

[3] McNeil's citations to *Time Warner Cable v. DIRECTV* and *Merck Eprova AG v. Gnosis S.p.A*, are unavailing because in each of those cases there was only one competitor. *Time Warner Cable,* 497 F.3d at 162 ("cable" as used in a given area must refer to Time Warner because Time Warner had the exclusive franchise in that area); *Merck Eprova, AG*, 760 F.3d 247 (2d Cir. 2014) (competitive claim must refer to plaintiff because the parties were the only direct competitors in markets). Flonase and Zyrtec are not the only competitors in the OTC allergy market, and more importantly, Zyrtec is not the only OTC single-ingredient allergy pills. *See* Kahlon ¶ 13. Thus, the presumption that a reference to an unnamed competitor necessarily means the plaintiff does not apply here.

advertisements differently, including by reference to brand popularity, brand awareness, frequency of doctor recommendations, and other metrics—none of which point to Zyrtec.[4] Kivetz ¶¶ 30-33. Where, as here, there is no single, unambiguously "correct" metric that consumers might apply to determine what a "number one" claim means, the claim cannot be literally false. *See*, *e.g.*, *Bridal Expo, Inc. v. van Florestein*, 08 CV 03777, 2009 WL 255862, at *7 (S.D. Tex. Feb. 3, 2009) (dismissing false advertising claim where ad claimed that Wedding Showcase was "Houston's #1 Bridal Show," without reference to category in which it was "# 1"); *Hill's Pet Nutrition, Inc. v. Nutro Products, Inc.*, 258 F. Supp. 2d 1197 (D. Kan. 2003) (finding "NATURAL CHOICE, #1 IN AMERICA'S PET STORES" ambiguous and that one reasonable interpretation of claim was literally true); *In re Century 21-RE/MAXReal Estate Adver. Claims Litig.,* 882 F. Supp. 915, 923 (C.D. Cal. 1994) (defendant's claim that it was #1 not actionable where it did not specify category).

Because McNeil does not—and cannot—prove that GSK's references to "the #1 allergy pill" are literally, necessarily, and unambiguously understood by consumers to be a reference to McNeil's products, McNeil's motion should be denied.

**2. Claritin Is The "#1 Allergy Pill" Under Various Interpretations Of Those Claims—Including McNeil's Own**

McNeil's motion fails for another reason: Zyrtec is not the "#1 allergy pill," including as defined by McNeil. In support of its motion, McNeil submits sales figures that it claims are "based ***in part*** on data reported by Nielsen through its Licensed Service for the Allergy Category for the 52-week period ending 2/14/15 for the U.S. market and through its Licensed Service for the Allergy Category for the calendar year-to-date ending 2/28/15 for the U.S. market." (Sellers

[4] Indeed, even McNeil implicitly admits that the term "#1 allergy pill" is subject to multiple reasonable interpretations. *See* Pls.' Mem. at 5 (suggesting several potential definitions, *e.g.*, gross dollar sales, gross unit sales, and unit sales equalized for dosage and pill count).

¶ 7 n.2.) Those numbers, however, are incomplete. It is indisputable that Nielsen data does not include sales figures from key segments of the retail market, including convenience stores, Costco and online vendors.[5] While Costco and online retail figures are not available, convenience store data is. And when those sales are considered, Zyrtec is not "#1" even under McNeil's theory, as shown in the above chart. Kivetz ¶ 17-18.

Zyrtec also lags behind Claritin in terms of brand awareness and loyalty, alternative metrics for defining the "#1 allergy pill." Kahlon ¶ 15. For instance, the 2014 U.S. Study of Allergies, a third-party survey designed to monitor allergy sufferers' treatment choices, found that Claritin surpassed Zyrtec in terms of brand awareness, doctor recommendations, and the percentage of respondents who had taken the product and had seen the product advertised. *Id.* Further, other third-party surveys in 2014 and 2015 found that Claritin had the highest level of consumer engagement *vis-à-vis* expectations in the category of OTC allergy medications. *Id.* ¶ 16.

McNeil is well aware of Claritin's market leading position, and has devoted its marketing strategy to attacking Claritin for that very reason. *Id.* ¶¶ 20-21. Indeed, on February 6, 2015, weeks after Flonase began using the "#1 allergy pill" claim, Ms. Sellers, McNeil's Group Brand Director, Allergy and Eyecare, repeatedly called Claritin as the "category leader" during a presentation she gave at the Association of National Advertisers' (ANA) 2015 Brand Masters Conference, according to an article summarizing that presentation. *Id.* ¶ 20. At that conference, Ms. Sellers, ***who signed a declaration in this case under penalty of perjury stating that Zyrtec is the #1 single-ingredient OTC allergy pill***, Sellers ¶ 7, talked about Zyrtec's strategy of targeting the "category leader," Claritin, a common marketing strategy. Kahlon ¶ 20. Ms.

[5] *See* http://www.cpgdatainsights.com/get-started-with-nielsen-iri/xaoc-and-mulo/ (discussing markets available from Nielsen and IRI).

Sellers was quoted as saying:

> We knew, on media, [Allegra] spent almost $150 million in the first year — double what ***category leader Claritin*** and Zyrtec spent together.

*Id.* Ms. Sellers detailed how McNeil set forth to "figure out how to get Claritin users to listen to us." *Id.* ¶ 21. McNeil conducted interviews with Claritin users and based on those interviews decided to target what they termed "Claritin Complacents." *Id.* Ms. Sellers was reported as saying that Zyrtec had narrowed the market share gap such that "on the eve of the ANA conference, the difference was down to half a point," an admission that Zyrtec continued to lag behind Claritin. *Id.* Similarly, in a recent submission for a marketing award, McNeil described its marketing campaign, "Muddle No More," as a direct attack on the stronghold that McNeil perceived Claritin to have on the large number of "Claritin Complacents": "In order to grow ZYRTEC®'s business, we needed to get users of other brands to try it. ***Claritin has more users than any other brand*** . . . ." *Id.* ¶ 22.[6] These statements directly contradict McNeil's litigation claims.

On this record, McNeil fails to establish the threshold requirement of showing clearly that GSK's references to "the #1" or "leading" allergy pill are unambiguously a reference to Zyrtec. As a matter of law, therefore, McNeil's motion should be denied in its entirety.

### C. The Flonase TV And Point-of-Sale Promotional Advertisements Do Not Make "Establishment Claims"

Recognizing that GSK's references to "the leading brand" and "the #1 allergy pill" are not literal and unambiguous comparisons to Zyrtec, McNeil seeks to take advantage of the lesser legal requirements for challenging so-called "establishment claims," which communciate to

[6] Insofar as McNeil challenges GSK's reliance on data provided by IRI, it is telling that McNeil itself (like countless other companies) has considered and relied upon IRI data, as admitted in its submission for the 2014 North American Effie Award. *Id.*

consumers that the claim specifically is "supported by a ***test*** or ***survey***." *Smithkline Beecham v. Johnson & Johnson-Merck*, 906 F. Supp. 178, 182 (S.D.N.Y. 1995). To this end, McNeil points to a single online advertiment on Walmart.com which references a "head-to-head trial" (Sellers Ex. L) to argue that ***all*** of GSK's advertisements are "establishment claims." Pls.' Mem. at 13-16.

McNeil's attempt to boot-strap all of GSK's Flonase advertisements into the realm of "establisment claims" based on one online advertisement is flatly contrary to Second Circuit law. When determining whether an advertisement is literally false, a court "*cannot consider…the defendant's prior advertising history*…." *JR Tobacco of America, Inc. v. Davidoff of Geneva (CT), Inc.*, 957 F. Supp. 426, 432 (S.D.N.Y. 1997) (*quoting Johnson & Johnson-Merck Consumer Pharmaceuticals Co. v. SmithKline Beecham Corp.*, 960 F.2d 294, 298 (2d. Cir. 1992)). Therefore, whether any particular Flonase advertisement is making an "establishment claim" must be made solely with reference to the words and context of each particular ad. Here, McNeil has shown that only one Flonase advertisement makes an establishment claim because only that one advertisement references a "study," "test," or "survey."

This issue is a red herring, however. As the Court recognized at the hearing on March 13, 2015, a full examination of the relevant scientific studies would not be appropriate within the time frame allotted to McNeil's motion. Hr'g Tr. 27:17-28:9. More importantly, contrary to McNeil's representation to the Court,[7] at least two large, peer-reviewed, double-blind, randomized, parallel group studies support that Flonase is statistically significantly more effective than Zyrtec in alleviating nasal symptoms associated with allergies. Dev ¶¶ 15-17. In addition, multiple national and international guidelines recommend intranasal corticosteroids,

[7] Compl. ¶4; Pls.' Mem. at 1("[T]here is no testing that demonstrates superiority for Flonase over either Zyrtec or Benadryl.").

such as Flonase, for nasal allergy symptoms, describing them as "***the most effective medication class*** for controlling symptoms of allergic rhinitis" and stating unequivocally that "intranasal corticosteroids are superior to antihistamines." *Id.* ¶ 9.[8] These recommendations were based in part on results from the robust head-to-head studies directly comparing Flonase to antihistamines, including Claritin and Zyrtec, showing that Flonase statistically significantly improved total nasal allergy symptoms relative to those other products. *Id.* ¶¶ 9-11. Even the much shorter study to which McNeil referred reflects that Flonase resulted it greater allergy symptom relief with Flonase compared to Zyrtec ***on all endpoints of the study*** trending to statistical significance at the end of that short study. *Id.* ¶ 18. On this record, even if GSK's advertisements referred directly to Zyrtec or could be considered establishment claims, McNeil would not be entitled to the "extraordinary and drastic remedy" of a preliminary injunction. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997).

**D. The "Six Inflammatory Substances" Claim Is Not Literally False**

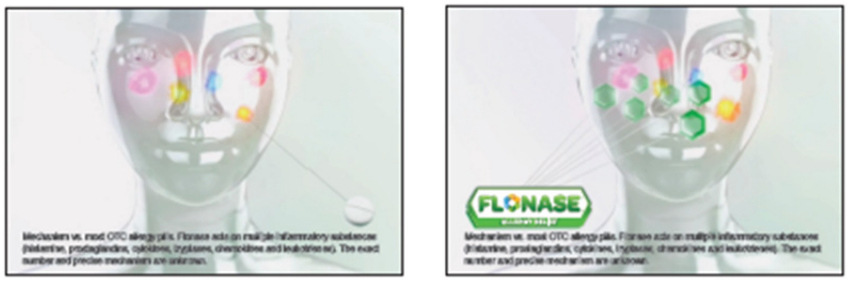
In asserting that GSK's "Six Inflammatory Substances" claim is false, McNeil makes no attempt to argue that this claim is literally false but falls back on a theory of "false by necessary implication." Tellingly, McNeil chose not to submit a video or storyboard of the Flonase commercial, but instead cherry-picked only a single phrase, taken out of context. Pls.' Mem. at 14-15. That doctrine does not advance McNeil's claims, much less its request for injunctive relief, because the words and context of GSK's advertisement simply do not literally, necessarily, and unambiguously convey that Flonase controls six symptoms, while the leading allergy pill controls only one. Kahlon ¶ 31.

[8] Further, in a case about the intranasal corticosteroid Nasacort, the National Advertising Division ("NAD") found that "intranasal corticosteroids as a class are the most effective medication class for controlling symptoms of allergic rhinitis" and that "Nasacort is comparable in efficacy to fluticasone propionate [Flonase]," which was shown to be superior to other OTC medications in relevant head-to-head studies. Kahlon ¶ 36.

Despite McNeil's continuous misleading reference to Flonase's "six inflammatory substances" language as the "Six Symptoms Claims," Pls.' Mem. at 14, *none* of GSK's ads refer to "six symptoms." Kahlon ¶ 32. To the contrary, the voiceover of the commercial states:

> When we breathe in allergens, our bodies react by overproducing six key inflammatory substances that cause our symptoms. The leading allergy pill only controls one. Flonase controls six, and six is greater than one.

*Id.* The illustrations, imagery and overall context of the Flonase commercial ***reinforces*** the truthful message as it shows a dramatization of how the body produces the inflammatory substances, which Flonase then targets:




*Id.* ¶ 31. The ads do not depict individuals suffering from symptoms—let alone six symptoms. Instead, the graphics carefully illustrate the allergens inflaming and producing the "six key inflammatory substances." *Id.*

Moreover, as with literal falsity, as a matter of law, a claim can only be "false by necessary implication" if the message argued to be implied is solely and unambiguously being conveyed. *Reed Const. Data Inc. v. McGraw-Hill Cos., Inc.*, No. 09 CV 8578, 2014 WL 4746130, at *18 (S.D.N.Y. Sept. 24, 2014) (internal citations omitted). If, however, the claim "is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false" even when a plaintiff is proceeding pursuant to the doctrine of false by necessary implication. *See Time Warner*, 497 F.3d at 158; *see also Buetow v. A.L.S. Enters. Inc.,* 650 F.3d 1178, 1185 (8th Cir. 2011) ("When an ad 'can reasonably be understood as conveying different

messages, [a] literal falsity argument must fail.'") (citation omitted); *see also Scotts Co. v. United Industries Corp.*, 315 F.3d 264, 275-76 (4th Cir. 2002) ("Because the graphic can reasonably be understood as conveying different messages, Scotts' literal falsity argument must fail."); *Zeltiq Aesthetics, Inc. v. BTL Indus., Inc.*, 32 F. Supp. 3d 1088 (N.D. Cal. 2014) (rejecting plaintiff's attempt to apply doctrine of false by necessary implication when advertiser, at most, told half-truth by claiming product was cleared by the U.S. Food and Drug Administration ("FDA") for one purpose without saying it was unapproved for another).

Here, McNeil's allegations about what Flonase's "six inflammatory substances" commercial conveys is not the necessary and only reasonable interpretation of the ad. To the contrary, one reasonable interpretation—indeed, the only *reasonable* interpretation—of the advertisement is exactly what the words of the commercial actually say. Specifically, that there are "6 key inflammatory substances that cause our symptoms." Kahlon ¶ 31. Critically, GSK adopted and uses the term "inflammatory substances" in connection with this claim because this term was specifically reviewed and approved by the FDA for use with GSK's prescription Flonase product. Dev ¶ 8.

McNeil's reliance on *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 947 (3d Cir. 1993) does not support its position. In that case, the Court determined that the ads linked the prevention of viscosity breakdown with the prevention of engine failure, and found the ad "false by necessary implication" because Pennzoil failed to prove that the difference in "viscosity breakdown" would actually cause engine failure. *Id.* at 948. Here, in contrast, there is no dispute that the "six inflammatory substances" referenced in the Flonase ads do, in fact, "cause our [allergy] symptoms"—exactly as the Flonase advertisements say. *Castrol*, therefore, is inapposite.

Because the "six inflammatory substance" claims are literally true and do not necessarily

and unambiguously convey six "symptoms" relieved compared to one, McNeil's motion as to these claims must be denied, as well.

## II. MCNEIL CANNOT ESTABLISH IRREPARABLE INJURY

Even if McNeil made a clear showing of likelihood of success on the merits, preliminary injunctive relief is an "extraordinary and drastic remedy" that is "never awarded as of right." *Winter*, 555 U.S. at 24 (citing *Munaf v. Geren*, 553 U.S. 674, 689-90 (2008)). Instead, McNeil must make a "clear showing" that it "is likely to suffer irreparable harm in the absence of preliminary relief," *Winter*, 555 U.S. at 20, 22; *see Salinger v. Colting*, 607 F.3d 68, 78-80 & n.7 (2d Cir. 2010). To meet its burden, McNeil argues only that it is entitled to a presumption of irreparable harm should it prove a likelihood of success on its allegations of literal falsity and that it will lose sales because of the challenged advertisements, which in turn will result in a loss of goodwill. (Pls.' Mem. at 9-10.)

Under well-established precedent, however, such cries of potential prospective harm are not enough. First, under the Supreme Court's decisions in *Winter* and *eBay, Inc. v. MercExchange*, 547 U.S. 388 (2006), presumptions of irreparable harm are no longer permissible. Rather, "plaintiffs must show that, on the facts of their case, the failure to issue an injunction would ***actually*** cause irreparable harm." *Salinger*, 607 at 82.[9] Second, the prospect of losing potential sales, standing alone, is insufficient to show irreparable injury. *See Euro-Pro Operating LLC v. Euroflex Ams.*, No. 08 CV 6231, 2008 WL 5137060, at *4 (S.D.N.Y. Dec. 8, 2008) (plaintiff need not show actual loss of sales to show irreparable harm but must show that

[9] While the Second Circuit has not yet applied *Winter* and *eBay* to false advertising cases, the *Salinger* panel stated that the Supreme Court's logic applies "with equal force to an injunction in *any* type of case," *id.* at 78 n.7 (emphasis in original), and district courts in this Circuit now routinely apply *Winter* and *eBay* to Lanham Act cases. *See, e.g.*, *Alpha Media Grp., Inc. v. Corad Healthcare, Inc.*, No. 13 CIV. 5438, 2013 WL 5912227, at *2 (S.D.N.Y. Nov. 4, 2013) (rejecting presumption in false advertising and trademark case); *Fresh Del Monte Produce Inc. v. Del Monte Foods Co.*, 933 F. Supp. 2d 655, 660 (S.D.N.Y. 2013) (false advertising case).

defendant's advertising "likely" has caused or will cause a loss of sales.) Not only are lost sales inherently *not* irreparable, but a plaintiff "must show more than a 'subjective belief' that it will be damaged." *Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 694 (2d Cir. 1994); *see also Reuters Ltd. v. United Press Int'l, Inc.*, 903 F.2d 904, 907 (2d Cir. 1990) ("Irreparable harm must be shown by the moving party to be imminent, not remote or speculative . . ., and the alleged injury must be one incapable of being fully remedied by monetary damages."); *Esbin & Alter, LLP v. Sabharwal Globus. & Lim, LLP*, 403 F. App'x 591, 592 (2d Cir. 2010) (insufficient showing of irreparable injury where "[i]t appears no evidence was submitted to the district court regarding [plaintiff's] loss of market share or clients following [defendant's] acquisition and use of the allegedly infringing software"). Finally, absent evidence of consumer perception (of which McNeil has none), McNeil cannot establish even the potential prospective loss of goodwill. As a result, McNeil fails to establish that it will suffer irreparable injury. *See Ortho Pharm.*, 32 F.3d at 696-697 (affirming denial of preliminary injunction where plaintiff did not provide consumer evidence).[10]

## III. GSK WILL SUFFER BOTH IRREPARABLE HARM AND SUBSTANTIAL HARDSHIP IF AN INJUNCTION WERE TO ISSUE

As the Second Circuit has explained, in considering whether to issue a preliminary injunction, "a court must consider the balance of hardships between the plaintiff and defendant

[10] The cases on which McNeil relies are inapposite. In *Reckitt Benckiser Inc. v. Motomco Ltd.*, 760 F. Supp. 2d 446 (S.D.N.Y. 2011), the court noted that "the allegedly false statements were made in the context of advertising campaigns directly referencing, and indeed aimed at, the opposing manufacturer's products," which were mentioned by name. *Id.* at 453. In *Zeneca Inc. v. Eli Lilly & Co.*, No. 99 Civ. 1452, 1999 WL 509471 (S.D.N.Y. July 19, 1999), the plaintiff's drug was the only drug on the market approved for the relevant use, and there was no ambiguity about whose drug was the subject of the challenged comparison. *See id.* at 32-33; 38. In *CJ Products LLC v. Snuggly Plushez LLC*, 809 F. Supp. 2d 127 (E.D.N.Y. 2011), the defendant sold counterfeit versions of the plaintiffs' product, and the plaintiff produced evidence of actual confusion in the form "customer reviews from Amazon.com showing that at least some consumers purchased defendants' product believing them to be plaintiffs' product." *Id.* at 145. Finally, the irreparable harm discussion in *North American Olive Oil Association v. Kangadis Food Inc.*, 962 F. Supp. 2d 514 (S.D.N.Y. 2013) is *dicta*; the court denied a preliminary injunction because the plaintiff's case failed on the merits for the same reasons McNeil's case fails here—the challenged statement was not unambiguously false and the plaintiff offered no evidence of consumer confusion. *Id.* at 520.

and issue the injunction *only if* the balance of hardships tips in the plaintiff's favor." *Salinger v. Colting*, 607 F.3d 68, 80 (2d Cir. 2010) (emphasis added). "[T]he balance of hardships inquiry asks which of the two parties would suffer most grievously if the preliminary injunction motion were wrongly decided." *Absolute Recovery Hedge Fund, L.P. v. Gaylord Container Corp.*, 185 F. Supp. 2d 381, 388 (S.D.N.Y. 2002) (citation omitted). McNeil cannot simply show that its own hardship is equal to that of GSK, but instead must show that McNeil's hardship is decidedly greater. *See Ottoman's v. Sunshine State Labs.,* No. 92 Civ. 5386, 1992 WL 212473, at *1 (S.D.N.Y. Aug. 24, 1992) ("[A]t best, plaintiff has shown that the hardship to either party is equal because although plaintiff may be harmed by the denial of the preliminary injunction, the defendants will be equally harmed if they are improperly enjoined from participation in the trade show"). McNeil does not make this showing.

As detailed in the Kahlon Declaration and as another court in this District has recognized, the launch period of a new product is absolutely crucial to its success. *See L & F Prods., a Div. of Sterling Winthrop, Inc. v. Procter & Gamble Co.*, 845 F. Supp. 984, 1004 (S.D.N.Y. 1994) ("The court further notes that the fact that defendant was broadcasting two of these commercials as an integral part of the product launch of two new consumer products, introduced to a highly competitive market only months before, tipped the balance of hardships ***strongly in favor of the defendant***."), *aff'd*, 45 F.3d 709 (2d Cir. 1995). During this period, consumers will first hear about the product and will be more likely to seriously consider it. Kahlon ¶ 41. Thus, it is vital that consumers have a positive impression of the product early on in order to build a customer base. *Id.* It also is important that retailers in this very competitive market have confidence in the product and its maker, and are not inconvenienced by the product launch. *Id.* After all, first impressions matter.

And, as McNeil knows, GSK has only a short window to make that first impression. The Spring allergy season is the first and most important allergy season of the year, and it lasts only from March until May. *See* Pls.' Mem. at 18. If the Court orders GSK to change its advertisements, GSK will effectively be foreclosed from advertising during the entire primary allergy season, and Flonase's reputation with consumers and retailers (which allocate shelf space) will irreparably be tainted. Kahlon ¶ 45. The issuance of a preliminary injunction at this point would be particularly detrimental because Flonase only has a limited period of time before generic versions of Flonase likely will be on the market, competing with Flonase. *Id.*; Dev ¶ 7. Thus, a preliminary injunction effectively would ruin Flonase's launch in irreparable ways.

Moreover, contrary to McNeil's unsubstantiated assertions that the "burdens and costs" to GSK would be "relative[ly] modest[]," halting a huge, multi-media national ad campaign is not so simple. As detailed in the Kahlon declaration, an injunction would require GSK to change [redacted] of in-store displays and [redacted] education boxes from stores. Kahlon ¶ 44. GSK would have to hire people to change the advertisements at [redacted] of retail locations, which would cost [redacted] and be extremely time consuming. *Id.* This would be an extremely burdensome, disruptive and costly undertaking, which would be devastating to the Flonase brand and would cripple its effective launch. *Id.* ¶ 43. Indeed, courts in this Circuit have acknowledged that "execut[ing] product alteration on a national scale"—including by distributing stickers to conceal allegedly misleading language—"[p]rior to an adverse determination on the merits . . . would pose serious hardship" to a defendant. *Silber v. Barbara's Bakery, Inc.*, 950 F. Supp. 2d 432, 445-46 (E.D.N.Y. 2013) (holding that balance of harms favors non-moving defendant); *see also L & F Products, a Div. of Sterling Winthrop, Inc.*, 845 F. Supp. at 1004 ("The court further notes that the fact that defendant was broadcasting two

of these commercials as an integral part of the product launch of two new consumer products, introduced to a highly competitive market only months before, tipped the balance of hardships ***strongly in favor of the defendant***."), *aff'd*, 45 F.3d 709 (2d Cir. 1995).

In short, the irreparable injury and enormous burden that GSK will face if an injunction issues firmly tips the balance of hardships in GSK's favor.

## IV. THE PUBLIC INTEREST WILL NOT BE SERVED BY ENJOINING GSK

McNeil does not show that an injunction favors the public interest. And, indeed, it cannot. Courts have long acknowledged the benefits of comparative advertising. *See Clorox Co. v. Stanson Detergents, Inc.*, No. 84 Civ. 1236, 1985 WL 275, at *1 (S.D.N.Y. Apr. 22, 1985) ("Comparative advertising is…in the public interest. It encourages competition and is an important source of information to consumers in making purchase decisions."). Because there are important differences between Flonase and other products, about which consumers should be aware, the public interest weighs against an injunction.

## CONCLUSION

For the foregoing reasons, McNeil's motion for preliminary injunction should be denied.

Dated: New York, New York
March 23, 2015

Respectfully submitted,

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